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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,703	12/30/2003	Jung San Huang	SLU 02-009	2134

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SAINT LOUIS UNIVERSITY
OFFICE OF INNOVATION AND INTELLECTUAL PROPERTY
3556 CAROLINE MALL
SUITE C208
ST. LOUIS, MO 63104

EXAMINER

STOICA, ELLY GERALD

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,703	Applicant(s) HUANG, JUNG SAN	
	Examiner Elly-Gerald Stoica	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-14,22-24,27-35 and 37 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-14, 22-24, 27-35 and 37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/27/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species unsaturated fatty acids and TGF- β in the reply filed on 10/01/2007 is acknowledged. The traversal is on the grounds that unsaturated and saturated fatty acids belong to a recognized class of molecules. This is found persuasive and the requirement for election of species with respect to the fatty acids is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Status of the claims

2. In the amended list of claims submitted on 10/01/2007, claims 4,5,15-21, 25, and 36 were cancelled. Claims 1-3, 6-14, 22-24, 27-35, and 37 are pending. Claims 1-3, 6-14, 22-24, 27-35 and 37 are subject to examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 14, 22, 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims 1, 22 and 37 are indefinite because they do not refer back to the preamble. It is also unclear if the methods recited in the claims 1, 22 and 37 are different methods or are the same.

For claims 14 and 35, where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). However, the recitation of a "sample" as being part of an animal is repugnant to the art and is considered unclear, so that the meets and bounds of the claims could not be determined.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 1-3, 6-14, 22-24, 27-35 and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

a) The specification ([0032]) describes "a sample" as follows:

"As used herein, the term "sample" means any mixture, solution, ex vivo tissue, in vivo tissue, blood, plasma, serum, biological extract, cellular extract, intact cell, interstitial space, mucosa, skin, skin surface or extracellular matrix. The preferred sample contains an α 2- macroglobulin or is in close proximity to an area, tissue or other sample that contains an α 2- macroglobulin. A preferred sample is from or in an animal. A preferred animal is a human". The arachidonic acid is an essential polyunsaturated fatty acid that is found in food of animal provenience or it may be synthesized in animal tissue from its

precursor, linoleic acid, which is an essential component of the majority of the vegetable oils used in human diet. Feeding constitute a natural act, since eating is essential function that is performed naturally and no regular diet can totally eliminate the fats. By ingestion of the arachidonic acid or vegetable oils or fats of any origin for that matter, a human would inherently practice the invention, since the arachidonic acid would act according to its properties and not to a set of desired intended uses.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6-14, 22-24, 27-35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by the public use.

As presented supra, the simple act of feeding would mean actually to practice the claimed methods of the invention. This fact was recognized even in the prior art as evidenced by the Das et al. (Mol. Cel. Biochem., 215, 145-152, 2000) which teaches that: "Polyunsaturated fatty acids seem to possess such a beneficial action. Gamma-linolenic acid, arachidonic acid, eicosapentaenoic acid and docosahexaenoic acid (GLA, AA, EPA and DHA respectively) can inhibit the production of IL-1, IL-2 and TNF and enhance the synthesis and release of TGF under some well defined circumstances both in vitro and in vivo" (p. 150, right col., lines1-9).

Art Unit: 1647

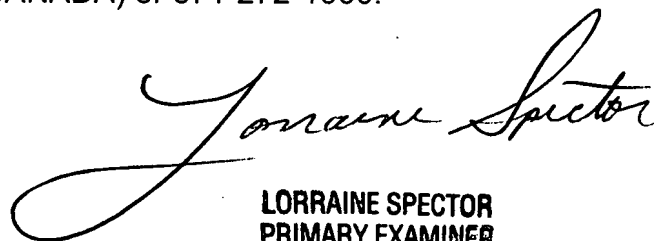
Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


**LORRAINE SPECTOR
PRIMARY EXAMINER**